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Paper No. 14

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FEB 1 1 2003

OFFICE OF PETITIONS

In re Application of
Davis, et al.
Application No. 09/725,030
Filed: November 29, 2000
Attorney Docket No. N/A
FOR: ANTI-S-PHASE TUBULIN LIGANDS

DECISION DISMISSING PETITION

This is a decision on the petition under 37 CFR 1.137(b), filed December 20, 2002, to revive the above-identified application.

The petition under 37 CFR 1.137(b) is **DISMISSED**.

Any further petition to revive the above-identified application must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Petition under 37 CFR 1.137(b)." This is **not** final agency action within the meaning of 5 U.S.C. § 704.

The above-identified application became abandoned for failure to timely reply to the non-final Office action, mailed December 27, 2001, which set a period for reply of three (3) months. Having obtained no extensions of time under 37 CFR 1.136(a), this application became abandoned on March 28, 2002. The filing of the instant petition precedes the mailing of A Notice of Abandonment.

A grantable petition to revive an abandoned application under 37 CFR 1.137(b) must be accompanied by: (1) the required reply (unless previously filed), which may met by the filing of a continuing application in a nonprovisional application abandoned for failure to prosecute, but must be the payment of the issue fee or any outstanding balance thereof in an application or patent, abandoned or lapsed for failure to pay the issue fee or any portion thereof; (2) the petition fee required by 37 CFR 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional; and (4) a terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)). This petition lacks item (1) above.

← Do they have one reply if so what's wrong?

With respect to (1), petitioners have not submitted an acceptable reply to the December 27, 2001 non-final Office action. Status requests will not suffice. An acceptable reply to the December 27, 2001 non-final Office action would be either an amendment or a continuing application. The application cannot be revived until an acceptable reply is submitted.

2.

#16

ARTICLE #1 OFFICE ACTION 12-27-01 09/725

09/725/030 WITH NUMBERED POINTS.

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Oct 18, 2001

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 3-7 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 3-7 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

1. Pursuant to the directives of paper No. 7 (filed 10/18/01), claims 1 and 2 have been cancelled, and claims 3-7 amended. Claims 3-7 are pending.

2. Applicants' species election (iodo-acetamido benzoyl ethyl acetate) is acknowledged ✓

3. The assumption at this point is that the phrase "in combination with claim 3" (claims 4-7) is intended to mean *a tubulin ligand according to claim 3*, rather than a mixture of two compounds. If this assumption turns out to be correct, the possibility of a revised restriction exists.

*

4. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(2) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as X formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate, and an amendment X to the first paragraph of the brief description of the drawings section of the specification which states:

> The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

5.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

*

5. If applicant desires priority based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. Thus, the following can be inserted following the title (on page 1 of the specification) but before the heading "Field of the Invention":

> This application is a continuation-in-part of application 09/258732, filed 2/26/99, now US Patent 6,294,695.

*

6. Claims 3-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,294,695. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d)

6.

*

7. The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

8. Claim 7 makes reference to treatment of various diseases. However, there is no evidence that even one of these can be effectively treated. The possibility does nevertheless exist that one or more of the following could become enabled, given appropriate evidence:

> The tubulin ligand according to claim 3, which is effective to inhibit proliferation of helminths.
>
> The tubulin ligand according to claim 3, which is effective to inhibit proliferation of trypanosomes.
>
> The tubulin ligand according to claim 3, which is effective to inhibit replication of a virus.
>
> The tubulin ligand according to claim 3, which is effective to inhibit growth of a fungus.

*

9. Claims 3-7 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9a

- Claim 3 recites the term "G1/S-phase". This term may be used, but only if accompanied by further explanation of its meaning.

9b

- Claim 3 is drawn essentially to a compound that causes a mechanism. How is it possible for any compound to cause a mechanism? A compound can certainly inhibit a biochemical process, or stimulate one; however, a compound cannot cause a mechanism. The following would be an improvement, although does not resolve all issues:

A tubulin ligand ~~that effects~~ G1/S-phase arrest of a cell.

Same as #3.

- Each of claims 4-7 recite the phrase "in combination with claim 3". The intended meaning is unclear. One possible interpretation is that applicants intend to refer to a mixture of two compounds. If this is not intended, claims 4-7 should be amended to clarify this. It is suggested that the following phrase be used in each of claims 4-7, if consistent with intentions:

A tubulin ligand according to claim 3...

10.

- The nomenclature used in claims 4-5 is somewhat ambiguous. For example, the name does not describe the position of the iodine atom (it could be present, for example, on the phenyl ring); as another example, the regiochemistry around the phenyl ring is not specified. It is suggested that applicants supply a structure in each of claims 4-5.

- Claim 6 is indefinite as to the intended derivative.

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

11 2.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11 cont'd

Claims 3, 6 and 7 are rejected under 35 U.S.C. §102(a) as being anticipated by Jiang (*Anti-cancer Drug Design* **13**, 735, 1998).

Not true HAHBC compounds only contained in Tab ligand

Jiang discloses the invention substantially as claimed.

Thus, the claims are anticipated.

[This reference was published in October of 1998. In applicants declaration (supplemental priority data sheet section), reference was made to application 09/258,732. However, application 09/258,732 was filed on 2/26/99, not in April of 1998. There is also no mention of provisional application 60/079,520 in applicants' declaration. Accordingly, the cited reference predates the filing of application 09/258732, and the inventive entity of the reference differs from that of the instant application].

multiple one

60 079 520 was not available to us

*

12 All but two of the references have been stricken from the IDS. None of the references have been received, although two of the references were nevertheless obtained by the examiner. It is suggested that applicants provide a copy of the remaining references.

1. None left

13 No claim is allowed. — definitive statement!

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

D. Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1800

9.

STATEMENT BY APPLICANT (use as many sheets as necessary)				Filing Date	
				First Named Inventor	Ashley Davis
				Group Art Unit	
				Examiner Name	
Sheet	1	of	1	Attorney Docket Number	

jc625 U.S. PTO 09/725030

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	1.1	A. Davis et al. Novel suicide ligands of tubulin arrest cancer cells in S-phase. Neoplasia, 1 (6), p.498-507. 1999.	
	1.2	Jaing J.D. et al. Synthesis, cancericidal and anti-microtubule activities of 3-haloacetamido-benzoyl-ureas. Anti-Cancer Drug Design, 13 (7), p.735-747. 1998.	
X	12	Jiang J.D. et al. 1998. Inhibition of microtubule assembly in tumor cells by 3-bromoacetylamino benzoylurea, a new cancericidal compound. Cancer Research, 58, p.2126-2133.	
X	13	Jiang J.D. et al. 1998. 3-iodoacetamido-benzoylurea A novel cancericidal tubulin ligand that inhibits microtubule polymerization, phosphorylates bcl-2 and induces apoptosis in tumor cells. Cancer Research, 58, 5389-5395.	
X	33	Shan B. et al. 1999. Selective covalent modificatio of beta-tubulin residue Cys-239 by T138067, an antitumor agentwith in vivo efficacy against multi-drug resistant tumors. Proc. Natl. Acad. Sci. USA, 96, (10) p. 5686-90.	

Examiner Signature	David Litten	Date Considered	12/21/01

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] Applicant is to place a check mark here if English language Translation is attached.

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